FEB 0 6 2002

Fukuda Denshi DYNASCOPE DS-5700
Special 510(k): Device Modification

Exhibit B
510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR part 807.92.

The assigned 510(k) number is: K020084.

Submitter:

Fukuda Denshi U.S.A. INC.
17725 NE 65th St. Building C
Redmond, WA 98052
Tel: 425-881-7737
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Contact Person:

Larry D. Walker
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FUKUDA DENSHI – Seattle Branch
17725 NE 65th St. Building C
Redmond, WA 98052
Tel: 425 881-7737
Fax: 425 869-2018

Date Prepared:

December 11th 2001

Device Name:

Proprietary Name:

FUKUDA DENSHI Dynascope model DS-5700 Central Station Monitor

Common Name:

Central Station Monitor

Classification Name:

Detector and Alarm, Arrhythmia

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Special 510(k): Device Modification

Exhibit B
510(k) Summary

Legally Marketed Device:

Fukuda Denshi DynaScope model DS-5800 NXMB Central Monitor Station: K000746

Description:

The DS-5700 is a microprocessor based software controlled device. The system consist of a central station includes a freestanding 18 inch color LCD display. Up to 16 patients can be centrally monitored simultaneously from the ICU,CCU or other areas of the hospital. Input signals are provided by Fukuda Denshi series patient monitoring equipment that have been submitted under separate 510(k) filings,

The DS-5700 is a true central station. All data is provided by external sources, Fukuda Denshi 5000 series patient monitoring equipment, for presentation and printout at central. The DS-5700 will act as a remote keypad for the bedside monitors, utilizing the touch screen capability of the LCD display, mouse or optional keyboard. The central station will act as a LAN administrator for monitors connected to the Fukuda Denshi patient monitoring LAN and display data from any sixteen of up to 64 bedside monitors.

The DS-5700 will present alarm information, ECG analysis and any other hemodynamic data acquired and processed by the bedside monitors.

Intended Use:

The device is intended to be used as a central station monitor for the evaluation of the cardiovascular system. It is intended to be used by or on the order of a physician or similar qualified health care professional. The DS-5700 is intended to be used in hospital environments: ER, ICU, a clinic, or similar settings. the device is intended to be used in those situations where the

patient is being monitored by a Fukuda Denshi DS-5000 series bedside patient monitor and remote central monitoring is desired. This device is not intended for home use.

Fukuda Denshi DYNASCOPE DS-5700
Special 510(k): Device Modification

Exhibit B
510(k) Summary

Technological Characteristics:

The DS-5700 incorporates the same fundamental technology as the predicate device. Data is acquired from "intelligent" bedside monitor via an Ethernet LAN and presented for display and/or printout. A touch screen LCD , mouse or keyboard offers the operator a means of entering information to the system and controlling the central station.

The technology characteristics of the DS-5700 do not affect the safety or efficacy of the device. Ay safety issues raised by a software controlled medical device are either the same issues already addressed by the predicate device or are addressed in the system hazard analysis or in the system validation.

K020084
p. 4/5

Fukuda Denshi DYNASCOPE DS-5700
Special 510(k): Device Modification
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510(k) Summary

Testing:

Laboratory testing was conducted to validate and verify that Fukuda Denshi Dynascope model DS-5700 Central Station Monitor meet all design specifications and was substantially equivalent to the Fukuda Denshi model DS-5300NXMB. The testing consisted of all environmental testing identified in the FDA's DCRND November 1993 "Reviewers Guidance Document for Premarket Notification Submissions". "Safe current limits for electromechanical devices", and ANSI/AAMI EC13 Cardiac monitors, health rate meters and alarms. Finally a hazard analysis of the system and software was performed and testing was conducted to validate the systems overall operation.

Although the device is neither life supporting nor life sustaining, diagnostic information derived for the use of the device may be critical to the proper management of the patient.

The areas of risk for this device are the same as other devices in this class and are the following:

1. Electrical shock to the user.
   - Excessive electrical chassis leakage current can disturb the normal electrophysiology of the heart and possibly leading to the onset of cardiac arrhythmias.
2. Misdiagnosis
   - Inadequate design of the data acquisition, display and printer output circuitry can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.
   - Inadequate design of the devices software can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

The design of the DS-5700 has taken into account all the above risk. This device is designed to meet UL 2601, CSA 22.2 and AAMI standards for

electrical safety for medical equipment. The tested device demonstrated that it was in compliance with these standards and that it meet it device specifications.

Fukuda Denshi DYNASCOPE DS-5700
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510(k) Summary

Conclusion:

The conclusions drawn from the laboratory testing the Fukuda Denshi model DS-5700 Central Station Monitor demonstrates that this device is as safe, as effective and performs as well or better than the legally marketed predicate device, Fukuda Denshi model DS-5800 NXMB, K000746

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 6 2002

Mr. Larry D. Walker
Regulatory Affairs Manager
Fukuda Denshi USA, Inc.
17725 NE 65th Street, Building C
Redmond, WA 98052

Re: K020084
Trade Name: Fukuda Denshi DYNASCOPE Model DS-5700
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: MHX
Dated: January 5, 2002
Received: January 10, 2002

Dear Mr. Walker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

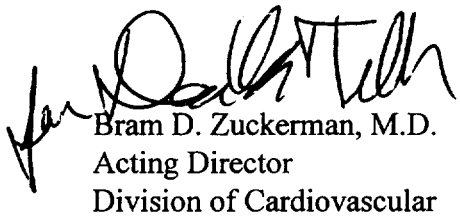
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Fukuda Denshi DYNASCOPE DS-5700
Special 510(k): Device Modification

Exhibit E
Indications of Use

510(k) Number (if known)	K 020084
Device Name	Fukuda Denshi Dyna Scope model Ds-5700 Central Station Monitor
Indications for Use	Use of the DS-5700 is indicated in those situations where centrally located hemodynamic monitoring of one or more patient's cardiovascular condition is desired and those patients are currently monitored at bedside by a Fukuda Denshi DS-5000 series bedside monitor. Use of this device is indicated only in a medically supervised healthcare environment. It is not for home use.

Prescription Use ✓
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020084